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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,692	04/17/2001	Motokazu Watanabe	43888-098	2364

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600 13th Street NW
Washington, DC 20005-3096

EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,692

Applicant(s)

WATANABE ET AL

Examiner

ALEX NOGUEROLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>05272004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 12 and 16 are rejected under 35 U.S.C. 102(a) as being anticipated by Yoshioka et al. (EP 0992589 A2), hereafter “Yoshioka.”

Yoshioka teaches a glucose sensor (abstract) comprising an electrically insulating base plate (1); and electrode system including at least a working electrode (4) and a counter electrode (5) formed on the base plate; and a reaction layer (8) containing at least pyrrolo-quinoline quinone dependent glucose dehydrogenase (claim 1) and at least one additive selected from the group consisting of gluconic acid and salts thereof (paragraphs [0015], [0029],[0036-0038], and [0042]), formed in contact or in the vicinity of the electrode system (Figure 2).

Yoshioka et al. does not mention whether “the response of the sensor immediately fabricated is substantially the same as compared to the sensor after being stored in a sealed container for one week at 40°C.” Barring evidence to the contrary, since the glucose sensor claimed by Applicant is structurally and compositionally the same as that taught by Yoshioka et al. the sensor disclosed by Yoshioka will inherently have the response property claimed.

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Although not needed for this rejection that the sensor of Yoshioka will have the claimed property is partially supported by Akio et al. (JP 09-262086), which teaches storing a glucose sensor comprising a reagent layer that includes a glucose enzyme and gluconate in a sealed container (claim 4, paragraph [0017] of *Means*, and paragraph [0024] of *Example*). Akio et al. teaches that after 1000 hours of being in a sealed container a glucose oxidase sensor had substantially the same response as before it was stored (presumably after being immediately fabricated).

Addressing claim 16, Yoshioka teaches a glucose sensor (abstract) comprising an electrically insulating base plate (1); and electrode system including at least a working electrode (4) and a counter electrode (5) formed on the base plate; and a reaction layer (8) containing at least pyrrolo-quinoline quinone dependent glucose dehydrogenase (claim 1) and gluconic acid (paragraphs [0015], [0029],[0036-0038], and [0042]), and phthalic acid (paragraph [0015]).

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-11 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshioka et al. (EP 0992589 A2), hereafter "Yoshioka," in view of the English language translation of Akio et al. (JP 09-262086), hereafter "Akio."

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Addressing Claim 1, Yoshioka teaches a glucose sensor (abstract) comprising an electrically insulating base plate (1); and electrode system including at least a working electrode (4) and a counter electrode (5) formed on the base plate; and a reaction layer (8) containing at least pyrrolo-quinoline quinone dependent glucose dehydrogenase (claim 1) and at least one additive selected from the group consisting of gluconic acid and salts thereof (paragraphs [0015], [0029],[0036-0038], and [0042]), formed in contact or in the vicinity of the electrode system (Figure 2).

Yoshioka does not mention placing the glucose sensor in a sealed container.

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Yoshioka does not mention storing the glucose sensor in a sealed container. Akio discloses a biosensor that has an electrode system and a reaction layer that includes glucose dehydrogenase and gluconic acid (the abstract; *Technical Field*; and paragraphs [0014]-[0016] of *Means*. Akio also teach storing the sensor in a sealed container (claim 4, paragraph [0017] of *Means*, and paragraph [0024] of *Example*). It would have been obvious to one with ordinary skill in the art at the time the invention was made to store the glucose sensor in a sealed container as taught by Akio in the invention of Yoshioka as modified by Akio because this will further help preserve the reaction layer paragraph [0017] of *Means* in Akio). The container seal will also prevent the reaction layer from being contaminated or wetted.

Addressing claim 2, Yoshioka also discloses including at least phthalic acid in the reaction layer (paragraph [0015]).

Addressing claims 3 and 6, Yoshioka also discloses including at least calcium ions in the reaction layer (paragraph [0038]).

Addressing claims 4, 7, and 8, Applicant should first note that claim 2 does not actually require a gluconate, gluconic acid could instead be present. In any event, if calcium ions are also present in the reaction layer (see the rejection of claim 3 above) then upon dissociation of gluconic acid calcium gluconate will also be present.

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Addressing claims 5, and 9-11, Yoshioka also discloses including a mediator in the reaction layer (paragraph [0029]).

Addressing claims 13, Yoshioka teaches a glucose sensor (abstract) comprising an electrically insulating base plate (1); and electrode system including at least a working electrode (4) and a counter electrode (5) formed on the base plate; and a reaction layer (8) containing at least pyrrolo-quinoline quinone dependent glucose dehydrogenase (claim 1) and at least one additive selected from the group consisting of gluconic acid and salts thereof (paragraphs [0015], [0029],[0036-0038], and [0042]), formed in contact or in the vicinity of the electrode system (Figure 2).

Yoshioka et al. does not mention whether “the response of the sensor immediately fabricated is substantially the same as compared to the sensor after being stored in a sealed container for one week at 40°C.” Barring evidence to the contrary, since the glucose sensor claimed by Applicant is structurally and compositionally the same as that taught by Yoshioka et al. the sensor disclosed by Yoshioka will inherently have the response property claimed.

Although not needed for this portion of the rejection that the sensor of Yoshioka will have the claimed property is partially supported by Akio which teaches storing a glucose sensor comprising a reagent layer that includes a glucose enzyme and gluconate in a sealed container (claim 4, paragraph [0017] of *Means*, and paragraph [0024] of *Example*). Akio teaches that after 1000 hours of being in a sealed container a glucose oxidase sensor had substantially the same response as before it was stored (presumably after being immediately fabricated).

Yoshioka does not mention placing the glucose sensor in a sealed container.

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Yoshioka does not mention storing the glucose sensor in a sealed container. Akio discloses a biosensor that has an electrode system and a reaction layer that includes glucose dehydrogenase and gluconic acid (the abstract; *Technical Field*; and paragraphs [0014]-[0016] of *Means*. Akio also teaches storing the sensor in a sealed container (claim 4, paragraph [0017] of *Means*, and paragraph [0024] of *Example*). It would have been obvious to one with ordinary skill in the art at the time the invention was made to store the glucose sensor in a sealed container as taught by Akio in the invention of Yoshioka as modified by Akio because this will further help preserve the reaction layer paragraph [0017] of *Means* in Akio). The container seal will also prevent the reaction layer from being contaminated or wetted.

Addressing claims 14 and 15, Yoshioka as modified by Akio does not mention having gluconic acid and glucose dehydrogenase within the claimed ranges of amounts; however, barring evidence to the contrary, such as unexpected results the amount of enzyme provided in the reagent layer will determined largely by (and be proportional to) the expected amount of analyte and the amount of gluconic acid provided in the reagent layer will in turn be determined by (and be proportional to) the amount of enzyme in the reagent layer.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Nogueraola
Primary Examiner
AU 1753
June 28, 2004